

### **Remarks**

The present communication responds to the Office Action dated March 8, 2007. In the Action, the Examiner rejected claims 2 and 4-26. The rejections are traversed for at least the reasons articulated below, and reconsideration is requested.

#### **Rejection under 35 U.S.C. § 102**

Claims 2, 4-6, 8-13, 18, 20-26 were rejected under 35 U.S.C. § 102(b) as anticipated by JP P2000-84078A ("Yasumichi").

#### **Independent Claims 4 and 20 are not Anticipated by Yasumichi**

Each of independent claims 4 and 20 include a limitation regarding a cannula or needle support comprising a thread turning in a first direction and another thread turning in a second, generally opposite direction. For example, claim 4 recites a cannula system comprising, in part, "a cannula support comprising a thread turning in a first direction and a another thread turning in a second, generally opposite direction."

Yasumichi does not disclose the invention of claims 4 and 20. Particularly, Yasumichi does not disclose a cannula support comprising a thread turning in a first direction and a another thread turning in a second, generally opposite direction. Rather, Yasumichi discloses an injection device which prevents easy detachment of a needle cap when not in use. *Yasumichi, Abstract*. The injector device of Yasumichi includes a small bore cylindrical part, an injector body, a needle mounting member, and a needle cap. *Yasumichi, Abstract*. The needle cap may be joined to the needle mounting member in a fitted state by a projection row. *Yasumichi, Abstract*. Additionally, in the fitted state, the needle cap is provided with a slope having a step capable of coming in contact with the a front stepped slope of the needle mounting member. *Yasumichi, Abstract*. Nowhere does Yasumichi disclose a threaded portion. Furthermore, nowhere does Yasumichi disclose a cannula support comprising a threaded portion.

Accordingly, Yasumichi does not disclose all elements of claims 4 and 20. Reconsideration and withdrawal of the rejection are requested.

Claims Depending from Claims 4 and 20 are Patentable

Because claims 2, 5-6, 8, and 21-26 depend directly or indirectly from claim 4 or claim 20 and incorporate all the limitations thereof, the preceding remarks obviate the basis for the rejection of the dependent claims under §102, i.e., every element of the claims is not disclosed by the cited documents. Reconsideration and withdrawal of the rejections are requested.

Independent Claims 9 and 18 are not Anticipated by Yasumichi

Each of independent claims 9 and 18 include a limitation regarding a cannula support comprising a latching element, wherein a cannula is temporarily/releasably covered when a protecting cap is coupled to the cannula support but not to the latching element and permanently/non-releasably covered when the protecting cap is coupled to the latching element. For example, claim 9 recites a cannula support comprising, in part, “a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap” and “wherein a cannula is releasably covered when the protective cap is arranged on the cannula support with no connection between the latching elements and wherein a cannula is covered in a substantially non-releasable manner when the protective cap is arranged on the cannula support with a connection between the latching elements.”

Yasumichi does not disclose the invention of claims 9 and 18. Particularly, Yasumichi does not disclose a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap and wherein a cannula is releasably covered when the protective cap is arranged on the cannula support with no connection between the latching elements and wherein a cannula is covered in a substantially non-releasable manner when the protective cap is arranged on the cannula support with a connection between the latching elements.

As discussed above, Yasumichi discloses an injection device comprising, in part, a needle mounting member and needle cap. *Yasumichi, Abstract*. In a fitted state, the needle cap is coupled to the needle mounting member by a projection row which engages a protrusion (element 17, Figure 4) as well as a stepped slope of the needle cap which engages a front stepped

slope of the needle mounting member. *Yasumichi, Abstract, Figure 4*. Thus, in the fitted state, each of the corresponding latching elements of the needle cap and needle mounting member are engaged. Yasumichi does not disclose a non-fitted state. Nor does Yasumichi disclose a moment in time when the needle cap covers a needle and wherein the projection row and stepped slope of the needle cap are not engaged with corresponding elements of the needle mounting member.

Accordingly, Yasumichi does not disclose all elements of claims 9 and 18, and reconsideration and withdrawal of the rejections are requested.

*Claims Depending from Claim 9 are Patentable*

Because claims 10-13 depend directly from claim 9 and incorporate all the limitations thereof, they are not anticipated by Yasumichi. Reconsideration and withdrawal of the rejections are requested.

*Rejection under 35 U.S.C. § 103*

Claim 7 was rejected under 35 U.S.C. § 103(a) as unpatentable over Yasumichi as applied to claim 4 and further in view of EP 0749760B1 (“Kakiuti”).

*Claim 4 is not Obvious Over Yasumichi in View of Kakiuti*

As discussed above, claim 4 is directed to cannula system comprising, in part, “a cannula support comprising a thread turning in a first direction and a another thread turning in a second, generally opposite direction.” As also discussed above, Yasumichi does not disclose the invention of claim 4.

Kakiuti does not remedy the disclosure deficiencies of Yasumichi. Kakiuti is directed to a prefilled or preloaded syringe, wherein a cartridge comprises the prefilled syringe and further comprises a needle holder on one end and a collar on the other end thereof. *Kakiuti, col. 6, ll. 1-7*. A thread is formed to the inner periphery of the collar such that a flange formed to a needle base engages the thread. *Kakiuti, col. 6, ll. 15-19*. Additionally, a cap may be attached to the needle holder. *Kakiuti, col. 6, ll. 20-21*. The cap is attached to the needle holder through one or

more projections which protrude from a tip of a flange of the cap and engage with an inner peripheral groove at the end of the collar. *Kakiuti*, col. 6, ll. 28-32.

Assuming for the purposes of argument that the needle holder of Kakiuti may properly be characterized as comprising a thread, Kakiuti merely teaches a needle holder comprising a single thread. Thus, Kakiuti does not teach or suggest “another thread” nor “another thread turning in a second, generally opposite direction,” as recited by claim 4.

Accordingly, none of Yasumichi, Kakiuti or the asserted Yasumichi/Kakiuti combination discloses or suggests a cannula support comprising a thread turning in a first direction and a another thread turning in a second, generally opposite direction.” Thus, claim 4 is not obvious over Yasumichi in view of Kakiuti.

*Claims Depending From Claim 4 Are Patentable*

Because claim 7 depends directly from claim 4 and incorporates all the limitations of claim 4, it is not made obvious by the Yasumichi/Kakiuti combination. Reconsideration and withdrawal of the rejections is requested.

*Claim 9 is not Obvious Over Yasumichi in View of MPEP 2144.04 VI Section B*

Claims 14-17 were rejected under 35 U.S.C. § 103(a) as unpatentable over Yasumichi as applied to claim 9 and further in view of MPEP 2144.04 VI Section B.

As discussed above, claim 9 is directed to a cannula support comprising, in part, “a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap” and “wherein a cannula is releasably covered when the protective cap is arranged on the cannula support with no connection between the latching elements and wherein a cannula is covered in a substantially non-releasable manner when the protective cap is arranged on the cannula support with a connection between the latching elements.” As also discussed above, Yasumichi does not disclose or teach the invention of claim 9.

The Examiner, citing MPEP 2144.04 VI Section B, asserts that mere duplication of parts has no patentable significance. As the above discussion traversing the rejection of claim 9 does

not involve duplication of parts, claim 9 is not obvious over Yasumichi in view of MPEP 2144.04 VI Section B.

Claims Depending from Claim 9 are Patentable

Because claims 14-17 depend directly or indirectly from claim 9 and incorporate all the limitations of claim 9, they are not made obvious by the Yasumichi/MPEP 2144.04 VI Section B combination for the same reason. Reconsideration and withdrawal of the rejection are requested.

Claim 19 is not Obvious Over Yasumichi in View of Kakiuti and Further in View of Sellar

Claim 19 was rejected under 35 U.S.C. § 103(a) as unpatentable over Yasumichi in view of Kakiuti and further in view of U.S. Patent 1,050,042 (“Sellar”).

Claim 19 recites a needle cover comprising, in part, “a needle support carrying a needle, said needle support comprising . . . an inside surface with an inside thread for coupling the support to an injection device” and “said needle support comprising a complementary counter thread whereby the outer protective cap and the needle support may be releaseably connected to each other, said counter thread turning in a direction generally opposite to the inside thread.”

As can be appreciated from the above discussion of the rejections of claims 4 and 20, none of Yasumichi, Kakiuti or the Yasumichi/Kakiuti combination teaches or suggests a needle support comprising an inside thread and a counter thread, nor wherein the counter thread turns in a generally opposite direction to the inside thread.

Sellar does not remedy the disclosure deficiencies of the Yasumichi/Kakiuti combination. Sellar discloses and teaches a “hypodermic syringe needle having an internally screw-threaded hub adapted to be screwed on an internally screw threaded glass nipple at the delivery end of a glass syringe barrel.” *Sellar, col. 1, ll. 9-13*. Sellar does not disclose or suggest a counter thread, or a counter thread turning in a generally opposite direction to the inside thread.

Accordingly, the asserted Yasumichi/Kakiuti/Sellar combination does not disclose or suggest a needle cover comprising a needle support with an inside thread for coupling the support to an injection device and a complementary counter thread whereby an outer protective cap and the needle support may be releaseably connected to each other, the counter thread

turning in a direction generally opposite to the inside thread. For at least this reason, claim 19 is not obvious over the asserted Yasumichi/Kakiuti/Sellar combination.

Conclusion

It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

In light of these remarks, the present application is in condition for allowance, and reconsideration and allowance are requested.

Respectfully submitted,

DORSEY & WHITNEY LLP  
Customer Number 25763

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By:

David E. Bruhn

David E. Bruhn, Reg. No. 36,762  
(612) 340-6317